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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/514,245	02/28/2000	Andre Justin	065691/0176	9396

7590

09/12/2002

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EXAMINER

SALIMI, ALI REZA

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 09/12/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/514,245

Applicant(s)

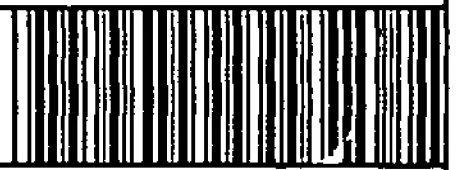
Justin et al

Examiner

A. R. SALMI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 10, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above, claim(s) 2, 3, 7-19, and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-6, 20, and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-22 are pending.

Raw Sequence Listing have been entered.

Submitted Information Disclosure Statement (I.D.S) is noted.

Notice of draftsperson's patent drawing review (PTO 948) is enclosed.

Election/Restriction

Applicant's election with traverse of Group I (claims 1-6, 20, and 22) in Paper No. 16 is acknowledged. The traversal is on the ground(s) that search and examination of other groups would not be unduly burdensome. This is not found persuasive because the separate classification of the subject matter is a prima facie showing of burden, which is not overcome by applicants' assertion to the contrary. Applicants further with traverse request consideration of all sequences, and indicate that MPEP permits examination of up to 10 distinct sequences. This is not persuasive, in the first fold the selection was not selection of species, since it was explicitly indicated that the sequences are considered independent and patentably distinct (see the previous action), which is not overcome by applicants' assertion to the contrary. The search for this case is considered to be highly burdensome, the adequate search has to be conducted in both in-house and commercial databases. Still further, the claims are not directed to only one sequence, the homologous sequences and fragments thereof also need to be searched. The information in

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databases almost double every few months, the office resources are now stretched to the limit, so only the selected sequence will be searched.

The requirement is still deemed proper and is therefore made FINAL.

Hence, claims 2, 3, 7-19, 21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected. Claims 1, 4-6, 20 and 22 are considered only within the scope of elected sequence.

The claims have been examined only to the extent of selected sequence designated as SEQ ID NO: 25. Applicants are requested to amend the claims accordingly by canceling the non-elected sequences.

Applicants are reminded to cancel the claims to the non elected claims.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on 12/05/1997. It is noted, however, that applicant has not filed a certified copy of the France 97/15396 application (a translation of the foreign application should be also be submitted) as required by 35 U.S.C. 119(b).

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Claim Rejections - 35 USC § 112

Claims 1,4-6, 20, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite, the intended nucleotide and its metes and bounds is not defined. In addition, the intended fragments or homologous is/are not defined. Is 10% identity or 5 amino acid long intended? This affects the dependent claims.

Claims 1, 4, and 5 are vague, indefinite and unclear for recitation of "homologous" or "at least 80% identity". The claims have been interpreted in view of the specification and it not clear what sequences are encompassed that at least have 80% identity or homologous. Identity, homology or sequence similarity can be calculated by a variety of different methods, whereby the calculated identity between two sequences will be quite different depending on the algorithm used for calculation. Applicant has referred to various % identities, but there are no indication of the utilized algorithm to calculate the identity sequences. Furthermore, the calculation of "identity" is affected by variables such as the relative weight given to the sequence gaps versus mismatches, or whether conservative substitutions are weighted differently from non-conservative substitutions. Since no art-recognized convention exists regarding the calculation of percent identity, the claims are vague and indefinite. Still further, in claim 4 the intended fragment(s) is/are not defined. This affects the dependent claim 6.

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Claim Rejections - 35 USC § 112

Claims 1, 4-6, 20, and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for induction of antibody response utilizing SEQ ID NO: 25, does not reasonably provide enablement for inducing a protective response (vaccine). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The scope of the claims read on a vaccine development. Applicants are reminded that the field of vaccine development is considered to be highly unpredictable. According to the specification and the state of the art the currently claimed virus attacks the immune system and disables the immune response. A vaccine is considered to be protective wherein upon re- introduction of the disease would be able to induce a long lasting protective response against a challenge. The current specification does not teach nor enables a vaccine to induce a protective response wherein upon introduction of the specific antigens or fragments thereof in to a host a protective response can be inferred. Absent teaching by the specification it would require undue experimentation for one ordinary skill in the art to enable the scope of the claims. The specification provides no teaching as to the induction of immunogenic protective response against the claimed antigenic fragments. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the invention. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is

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concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-6, 20, and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant disclosure, the applicants have only disclosed the sequences identified as SEQ ID NO: 25. No other homologous sequences or fragments thereof were disclosed. There is no information in the specification that applicants were in **possession** of the claimed sequences. In addition, there is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the undisclosed homologous regions or where the region, fragments may encompass. Therefore, a written description of the all other claimed sequences of Circovirus type B should be disclosed to overcome this rejection. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which

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teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that a patent specification contain a written description of the invention and the manner and process of making and using it "in such full clear and concise terms as to enable one skilled in the art ... to make and use" the invention. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997):

The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA Accordingly, the specification does not provide a written description of the invention

and at pg 1406:

a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the

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genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page

1021:

A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-6, 20 and 22 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Meehan et al (J of Gen. Virology, 1997, vol. 78, pp. 221-227).

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The polypeptide and the nucleotide sequence disclosed by the above cited article meets the limitations of the claimed invention. In addition it also meets the limitations of derived and fragments. The above cited art meets the limitations of broad homologous limitation including 80% homologous, and immunogenic fragments of the claimed limitation. Alternatively, it would have been obvious to one ordinary skill in the art to derive polypeptide from the disclosed sequence and utilize the fragments to enhance immune response. The ordinary skilled artisan being familiar with the state of the art and the cited article would not have anticipated any unexpected results. The claims are deemed *prima facie* obvious absent unexpected results.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published

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under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Allen et al (US Patent No. 6,368,601 B1).

The teaching and claims of the above cited patent meets the broad recitation of the claims (see for example claim 26).

Claims 1, 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Poet et al (US Patent No. 6,287,856 B1).

The teaching and claims of the above cited patent meets the broad recitation of the claims (see for example claim 1).

Allen
Claims 1, 4-5, 20 , 22 are rejected under 35 U.S.C. 102(e) as being anticipated by
~~Poet~~ et al (US Patent No. 6,217,883B1).

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The teaching and claims of the above cited patent meets the broad recitation of the claims (see claims 1, 4, 5, 28). Also, the SEQ ID NO: 1 meets the broad limitations of the 80% limitation of claimed invention.

No Claims are allowed.

Conclusion

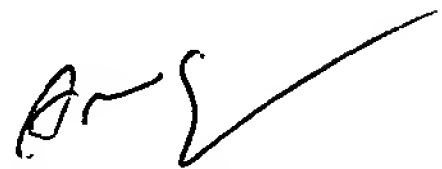
Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

9/10/2002


ALI R. SALIMI
PRIMARY EXAMINER